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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,746	02/20/2002	Antonio Facchiano	2507-1003	3449

466 7590 03/31/2005

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/077,746	FACCHIANO ET AL.	
	Examiner	Art Unit	
	Sheridan K. Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 5-11 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Response to Amendment

1. This Office Action is in response to Paper filed 3/01/2005. Applicant's amendment of claims 1-11 is acknowledged. Applicant's addition of new claim 12 is acknowledged. Claims 1-4 and 12 are under examination.

Withdrawal of Objections and Rejections

2. The objections and/or rejections not explicitly restated or stated below are withdrawn.

Maintained Objections and Rejections

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2- 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 2-4 are directed to a genus of peptides homologous to the peptide of SEQ ID NO: 1 with respect to several physical or structural properties such as sequence homology, electric-charge homology or functional group disposition, for example. The specification discloses the sequence SEQ ID NO: 1 and concepts regarding the meaning of "percent" (%), however, there is no description of functional differences brought about by a percent similarity

Art Unit: 1653

difference (e.g., if there is a similarity difference of 73, 86 or 92%) that would result in a biologically active protein possessing a desired function. Thus, no relationship between the structural properties and functional properties is established. Furthermore, claims 3 and 4 recite properties of the peptide sequence of SEQ ID NO: 1 that is not supported in the specification. No guidance is provided as to what electric-charge homology, hydrophilia, hydrophobicity, solvent-exposure rate, or functional group disposition.

Therefore, only isolated peptides comprising the amino acid sequence set forth in SEQ ID NOs: 1, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph.

4. Applicants argue at page 6 of the response that the above rejection fails to meet the burden of showing that the disclosure fails to meet the written description requirement in that the peptide of the claims are “identified by their structure, properties, and/or function.”

Applicant's arguments have been fully considered, but they are not persuasive. As indicated above, the present specification do not support the entire genus recited by the claims. Thus, the applicant is not in possession of that genus. The specification discloses the sequence SEQ ID NO: 1 and concepts regarding the meaning of “percent” (%), however, there is no description of functional differences brought about by a percent similarity difference (e.g., if there is a similarity difference of 73, 86 or 92%) that would result in a biologically active protein possessing a desired function. Thus, no relationship between the structural properties and

Art Unit: 1653

functional properties is established. As a result, the full breath of the genus cannot be envisioned.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Baird *et al.* (US 5,252,718). Baird *et al.* teaches a peptide that comprises a sequence 100% identical to SEQ ID NO: 1 (See Example 1, bFGF from amino acid 25-35, for example; see also attached sequence alignment)(Note: “having” as recited in the claim is interpreted as “comprising”). The peptide of Baird *et al.* would thus comprise all of the properties, such as electric-charge homology or conformation similarity, inherent to the amino acid sequence of SEQ ID NO: 1. Thus, the reference clearly anticipates the invention as recited in the claims.

6. Applicant's arguments have been fully considered but they are not persuasive. Applicant arguments regarding the functional distinction between the recited peptides and those of Baird *et al.* are compelling. However, it is noted that none of these functional properties are present in the claim language. As such, the peptides of Baird *et al.* are encompassed by the literal interpretation of the recited claims.

Conclusion

7. Claims 12 is in condition for allowance.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for regular

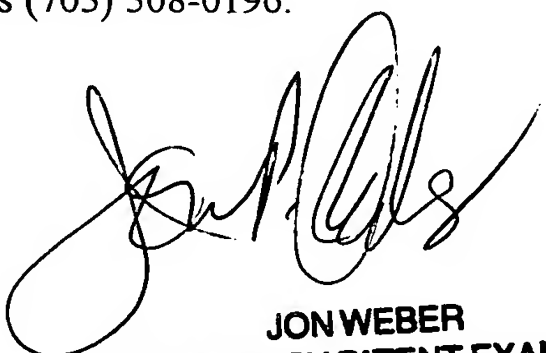
Art Unit: 1653

communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS

March 23, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER